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ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Progress and Highlights in the EHS Programme

58th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology

6-8 November 2018, at the OECD Conference Centre, 2 rue André Pascal, Paris, beginning at 09h30 on 6 November

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This document provides an update on progress made since the last Joint Meeting in the work areas of the Environment, Health and Safety Programme which are not the subject of a specific agenda document at this Joint Meeting.

ACTION REQUIRED: ***The Joint Meeting is invited to:***

i) take note of the progress report; and to

ii) take any further action as appropriate.

General Issues

Environment Policy Committee

1. The Environment Policy Committee met on 16-18 April 2018 at OECD Headquarters in Paris [ENV/EPOC/M(2018)1/FINAL]. The main topics discussed were:

- The 2019-2020 Programme of Work and Budget;
- Revision of the Council Recommendation of on Environmental Impact Assessment;
- Contribution to the Ministerial Council Meeting;
- RE-CIRCLE Project: Draft Projections of Materials Use to 2060 and their Economic Drivers;
- Joint Work by the Joint Meeting and EPOC.

2. EPOC agreed the 2019-2020 Programme of Work and Budget (PWB), which includes the Part I PWB of EHS. Regarding the joint work of EPOC and the Joint Meeting, EPOC:

- Recalled the desire of EPOC and the Joint Meeting to enhance linkages between their work programmes.
- Noted the development of four areas of work that are currently on-going: socio-economic analysis of chemicals management and valuation of negative health impacts; contaminants of emerging concern in surface water; sustainable plastics from the chemicals' point of view; and environmental performance review of chemicals management.
- Expressed support for the co-operation, and several delegates specifically advocated for the socio-economic analysis of chemicals management and valuation of negative health impacts and for the standardisation of chemicals-related analysis within the Environmental Performance Reviews.

Ministerial Council Meeting

3. The Meeting of the OECD Council at Ministerial Level took place on 30-31 May 2018 at OECD Headquarters. The Statement of the French Chair of the meeting specifically mentions the work of the Joint Meeting on sustainable plastics [http://www.oecd.org/mcm/documents/Statement-French-Chair-OECD-MCM-2018.pdf] in section 6 Climate and the Environment:

- "[…] *They underline the need to fully understand, prevent and reduce the impact of plastics waste and the chemicals used in their manufacturing on the environment, especially in the oceans, and human health, and to adopt a life-cycle approach for plastics management. Building on earlier OECD work on Extended Producer Responsibility, they ask the OECD to undertake new work on the value*

chain of plastics with a view to reducing their impacts and maximising economic effectiveness of policy responses, and to pursue in greater depth its work into assessing chemical-related risks. [...]"

IOMC

4. The IOMC met on 10 May 2018 in Washington, D.C. The meeting was preceded by a retreat on 8-9 May to discuss the role of IOMC in the development and implementation of the post-2020 framework for the sound management of chemicals and waste.

IOMC retreat (8-9 May 2018)

5. The IOMC Participating Organisations (POs) agreed that "coordination" will remain the focus of the IOMC in the future and that "coordination" covers:

- avoiding duplication between Participating Organisations;
- exploiting synergies;
- respecting each other's unique skills and contributions;
- joint planning and action;
- information exchange;
- networking;
- filling gaps;
- having a common purpose and impact;
- leveraging funding.

6. The IOMC agreed to become more active on the following new topics or areas of work in the future:

- Waste, in the context of chemicals in products and the circular economy;
- Soil and air pollution;
- Substitution and Alternatives (including non-chemical solutions).

7. The new vision statement of the IOMC will be: "The IOMC shapes a sustainable future through coordinated global action to achieve the sound lifecycle management of chemicals and waste for healthy lives and the environment."

IOMC meeting (10 May 2018)

8. Emerging Policy Issues: the IOMC will consider developing a project proposal under GEF7 for addressing Highly Hazardous Pesticides. UN Environment will draft a workplan for addressing Environmentally Persistent Pharmaceutical Pollutants (EPPP), based on the model for Endocrine Disrupting Chemicals.

9. 3rd Open-Ended Working Group (OEWG) of the International Conference on Chemicals Management (ICCM): It will probably be held during the week of 1 April 2019 in Uruguay. WHO will propose to hold a side-event on their chemicals road-map. OECD proposed to hold IOMC side-events on EPPP and on illegal trade of pesticides,

given the upcoming OECD results on these topics. The IOMC decided to prepare the following documents for OEWG3:

- Progress reports on Emerging Policy Issues;
- Progress against the IOMC indicators;
- Waste i.e. what type of work the IOMC could coordinate under the new international framework beyond 2020.

1. Provision of knowledge and information

1.1. Methodologies for Hazard Assessment (including Integrated Approaches to Testing and Assessment and cooperative hazard assessments)

1.1.1. Integrated Approaches for Testing and Assessment

10. The Integrated Approaches to Testing and Assessment (IATA) case studies project continues under a project team of the Working Party on Hazard Assessment.

11. The following four case studies were published in September 2019:

- Estrogenicity of Substituted Phenols [Canada & the United States]
- Prioritisation of chemicals using the Integrated Approaches for Testing and Assessment (IATA)-based Ecological Risk Classification [Canada]
- Case study on grouping and read-across for nanomaterials genotoxicity of nano-TiO2 [JRC]
- A Case Study on the Use of Integrated Approaches for Testing and Assessment for Sub-Chronic Repeated-Dose Toxicity of Simple Aryl Alcohol Alkyl Carboxylic Esters: Read-Across [ICAPO]

12. The following two case studies have been submitted in the fourth review cycle.

- Read-across based on metabolism and AOP information focusing on testicular toxicity [Japan]
- Use of a Defined Approach for Identifying Estrogen Receptor Active Chemicals [US]

13. These case studies will be discussed at the 4th Meeting of the IATA Case Studies Project to be held in 27 November 2018 in order to identify lessons-learned and areas for further development of guidance. In addition, the project team will have a joint meeting with the QSAR Toolbox Management Group to discuss QSARs in the context of a defined approach for skin sensitisation.

14. A new project to develop an Overview Document on Concepts and Available Guidance for Integrated Approaches to Testing and Assessment (IATA) and their Components was launched in January 2018. The document will serve as an overarching reference document for IATA and give an overview of existing guidance on IATA, IATA components and relating cross-cutting topics. A draft document will be discussed at the 4th meeting of the IATA Case Studies Project.

1.1.2. QSAR Toolbox

15. The European Commission – DG Joint Research Centre (JRC), the US Environmental Protection Agency and the OECD Secretariat work together on the development of the AOP Knowledge Base (AOPKB) v2.0. The project will proceed in three phases: a) Requirements capturing, b) System specifications, and c) System development. The first phase is led by the JRC and the study/survey is anticipated to deliver results in spring 2019.

1.1.3. Combined Exposures to Multiple Chemicals

16. A project team under the Working Party on Hazard Assessment and the Working Party on Exposure Assessment continues to work on the topic of assessing risks from the combined exposures to multiple chemicals. A draft guidance document has been developed on considerations for problem formulation, hazard assessment, exposure assessment, and risk characterisation. The document is currently under endorsement by the Working Parties. It is expected that the document will be published in late 2018.

1.1.4. Weight of Evidence

17. A new project was started to develop a document with *Guiding Principles for Establishing Weight of Evidence for Chemical Assessment*. The project aims to establish basic guiding principles to formulate a weight of evidence (WoE) for both the prioritisation and assessment of chemicals under different regulatory and non-regulatory contexts. The document is expected to be submitted to the Working Party on Hazard Assessment for comments and approval in June 2019.

1.1.5. Physiologically Based Kinetic Models

18. The development of a guidance document on the characterisation, validation and reporting of physiologically based models for regulatory applications was initiated. This project is a joint initiative between the Working Party on Hazard Assessment and the Extended Advisory Group on Molecular Screening and Toxicogenomics. A face-to-face meeting of the expert group took place in September 2018 to discuss the case studies and progress with the drafting of the guidance document. It is expected that the document will be finalised in Q2 2019.

1.1.6. Priority Setting

19. The development of a document to capture international best practices for identifying priorities for risk assessment was initiated in January 2018. This project commenced with a survey of priority setting frameworks and tools used in countries.

Forthcoming events:

- 3rd Meeting of the Working Party on Hazard Assessment, week of June 19, 2019, OECD, Paris.
- 4th Meeting of the IATA Case Studies Project, 27 November 2018, OECD, Paris
- Joint Meeting of the IATA Case Studies Project and the QSAR Toolbox Management Group, 28 November 2018, OECD, Paris

- 15th Meeting of the QSAR Toolbox Management Group, 29-30 November 2018, OECD, Paris

Contact: *Eeva Leinala, Magdalini Sachana, Masashi Horie, Valérie Frison. AOP-KB and Effectopedia: Anne Gourmelon, Magdalini Sachana.*

Websites:
www.oecd.org/env/ehs/risk-assessment/hazard-assessment.htm
www.oecd.org/chemicalsafety/risk-assessment/iata-integrated-approaches-to-testing-and-assessment.htm

1.2. Exposure Assessment (including exposure to children)

1.2.1. Estimating the release of chemicals

20. The Working Party on Exposure Assessment (WPEA) is currently developing nine Emission Scenario Documents (ESDs) or related documents:

1. Release of plastic additives during the use of end products: Complementing document to the ESD on plastic additives,
2. ESD on smelting and disposal of metals used in electrical and electronic products,
3. ESD on chemical additives used in automotive lubricants,
4. ESD for the use of aqueous film forming foam,
5. Compilation of case studies of uses of fluorocarbon substitutes in refrigeration, air conditioning, electronics, metal cleaning and foam blowing,
6. ESD for chemicals used in hydraulic fracturing,
7. ESD for the use of vapour degreasers,
8. ESD on chemicals used in fabric finishing, and
9. ESD on compounding of carbon nanotubes

21. The draft ESD on plastic additives was discussed at the Second Meeting of WPEA in September 2018, and is expected to be finalised in Q4 2018.

22. In addition, the WPEA published in September 2018 a matrix on the relationship between lifecycle stage and use descriptors to analyse similarities and differences between the OECD ESDs and the EU Specific Environmental Release Categories (SpERCs). This project was led by Japan.

1.2.2. Combined exposure to multiple chemicals

23. A project team under the Working Party on Hazard Assessment and the WPEA continues to work on the topic of assessing risks from the combined exposures to multiple chemicals. A draft guidance document has been developed on considerations for problem formulation, hazard assessment and exposure assessment, and risk characterisation. The document is currently under endorsement by the Working Parties. It is expected that the document will be published in late 2018.

1.2.3. Exposure to humans and the environment

24. The WPEA developed a "Product Release and Exposure Data Warehouse", led by the United States, designed to house existing data on releases from, and exposures to, chemicals used in commercial and consumer end products. This database is expected to be published in November 2018.

25. The WPEA is also discussing issues around children's health with two projects. The first project aims to develop a decision tree to determine the need for specific exposure assessments for children using relevant case studies. This decision-tree is expected to be published in Q2 2019. The second project aims to develop an *in silico* exposure tool that facilitates estimation of oral exposures of children via the mouthing of objects and to develop an associated guidance document. The guidance document on oral exposure is expected to be finalised in Q4 2018.

26. To improve and further develop wastewater treatment removal prediction methods, Canada as lead country initiated an experimental study to measure half-lives of different types of chemicals under activated sludge conditions.

27. The WPEA is also working on the development of a biomonitoring database on chemicals measured in humans. The project is done in close collaboration with the EU's IPCheM project to make use of possible synergies.

28. The WPEA also launched a new project on dermal exposure and absorption in June 2018.

Forthcoming events:

- Second Meeting of the Working Party on Exposure Assessment (June 2019, Paris, France)

Recent Publications in the Series on Testing and Assessment:

- No 294: Matrix Between Emission Scenario Documents (ESDs) and Specific Environmental Release Categories (SpERCs)

Contact: Takaaki Ito

Websites: **http://www.oecd.org/env/exposure**
http://www.oecd.org/chemicalsafety/childrens-health.htm

1.2.4. Project on Best Available Techniques

29. A new project on Best Available Techniques (BAT) for preventing and controlling industrial chemical pollution started in 2016. Its aim is to assist governments in implementing policies and practices that embody BAT or similar concepts to prevent and control industrial emissions. The project consists of three activities: (i) information sharing on policies and practices that embody BAT; (ii) information exchange on how governments collect information on techniques and identify BAT; and (iii) evaluation of the effectiveness of the use of BAT by using PRTR information or monitoring data.

30. A survey to collect general information regarding how countries establish BAT policies was conducted. Data was also gathered through country visits (to India and the

People's Republic of China) and comprehensive exchange with national experts. A draft report based on the collected information was reviewed at the Second Meeting of the Expert Group on BAT in November 2017. The final report was published in June 2018.

31. For the third part of the project, information was collected through a survey and subsequent interviews and discussions with national experts. The draft report was reviewed at the Third Meeting of Expert Group on BAT in October 2018. The final report is expected to be declassified by early 2019.

Recent Publications in the Series on Testing and Assessment:

- Best Available Techniques for Preventing and Controlling Industrial Pollution – Activity 2: Approaches to Establishing Best Available Techniques (BAT) Around the World (Mono – Glossy)

Contact: *Takaaki Ito, Marit Hjort*

Web site: **http://www.oecd.org/chemicalsafety/risk-management/best-available-techniques.htm**

1.3. Approaches for determining the Safety of Manufactured Nanomaterials

1.3.1. Testing and Assessment

32. The WPMN continues its assessment of the test methods used in the Testing Programme. The European Chemicals Agency (ECHA) is leading an evaluation of the applicability of in vivo methods for human health and the environment that were applied in the Testing Programme. This work is still underway and the next steps are expected to be discussed by the steering group on Testing and assessment.

33. In parallel, progress continues in reviewing and developing Test Guidelines for nanomaterials. In June 2018, the revised OECD Guidance Document 39 on Inhalation Toxicity was published to incorporate guidance for testing nanomaterials.

34. Furthermore, two project proposals for (new) Test Guidelines on physical chemical properties of nanomaterials, were finalised and submitted to the WNT. These were approved and included in the Programme of Work of the WNT.

35. Seven new proposals for Test Guidelines and Guidance Documents for nanomaterials have been included in the WPMN programme of work with a view to prepare project proposals to be submitted to the WNT in 2019. The WNT was updated on the activities of the WPMN in April 2018 to ensure close collaboration between WPMN and WNT National coordinators, as well as a smooth collaboration between the two bodies.

36. As for work on Exposure Measurement and Exposure Mitigation, the objective of this activity is to exchange information on (or develop) guidance for exposure measurement and mitigation. The WPMN started a project for the "Compilation of available tools and models used for assessing environmental and consumer exposures to NMs" led by Canada. Progress was presented and discussed at WPMN18 in February 2018. The WPMN reviewed the compilation of models and agreed to assess the models for their use in risk assessment. A draft was prepared by Canada and has been circulated

for comments to the WPMN in October 2018. In addition, Denmark made a proposal for complementing this review by incorporating models used for occupational exposure. Progress on this project will be presented and discussed at WPMN 19 in February 2019. A meeting of the steering group on exposure was hosted by Canada in August 2018. This meeting allowed for the review of projects underway and delegates identified potential areas of collaboration with the Working Party on Exposure Assessment. A number of recommendations for possible future work will be presented and discussed at the WPMN in February 2019.

37. The WPMN is also undertaking a new project entitled Moving Towards a 'Safer Innovation Approach' for More Sustainable Nanomaterials and Nano-enabled Products: Overview of existing risk assessment tools and frameworks, and their applicability in industrial innovations (the 'SIA project'). Following in-depth discussions held in 2016/17 and successive drafts, the final revised proposal was formally approved in April 2018. The SIA project is co-led by France, the Netherlands and BIAC. An Ad hoc expert group was established, with 11 participating delegations. A detailed working plan is being prepared, organised in three main tasks for implementing the project: (1) Safe-by-design terminology and working definitions; (2) Available risk assessment tools, frameworks and initiatives; and (3) Analysing regulatory strategies for awareness and decisions. Progress made on data collected as well as first text elements already developed will be reported to the WPMN meeting in February 2019.

Forthcoming events:

- 19th Meeting of the Working Party on Manufactured Nanomaterials, 19-22 February 2019 Paris, France

Publications in the Series on Manufactured Nanomaterials*:*

- No. 88 - Investigating the Different Types of Risk Assessments of Manufactured Nanomaterials
- No. 87 - Developments in Delegations on the Safety of Manufactured Nanomaterials - Tour de Table
- No. 86 - Assessment of Biodurability of Nanomaterials and the Surface Ligands
- No. 85 - Evaluation of in vitro methods for human hazard assessment applied in the OECD Testing Programme for the Safety of Manufactured Nanomaterials

Contacts: *Peter Kearns, Mar Gonzalez, Tatsuki Izawa, Bertrand Dagallier, Jeeyoung Kim, Emily Seftel*

Website: **www.oecd.org/chemicalsafety/nanosafety**

1.4. Notification and reporting tools

1.4.1. OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs)

38. The work continued to adapt the OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs) to new or revised Test Guidelines. Four OHTs on

health effects (dealing with acute toxicity–inhalation, acute toxicity–dermal, repeated-dose toxicity–inhalation, and genetic toxicity *in vivo*) and one OHT on biotic system effects (toxicity to micro-organisms) were updated, endorsed by the Joint Meeting in July 2018 and published on the website in September 2018. A new template on dispersion stability of nanomaterials was developed for the Series on degradation/accumulation (environmental fate and behaviour); having gone through successive revisions, its final draft is expected to be presented to the Joint Meeting for endorsement by the end of 2018/early 2019. The next batch of updates to four OHTs on health effects (eye irritation, skin sensitisation, repeated-dose toxicity–oral and teratogenicity) will start in the coming weeks.

39. Led by the European Union, the project aiming to extend the current 'OHT 201 on Intermediate Effects' to cover the reporting of tests made according to OECD *In vitro/In chemico* Test Guidelines, is in progress. This will orientate future updates of OHTs when dealing with reporting of non-apical observations from *in vitro* tests. The principle of individually reporting intermediate effects in OHT 201 instead of within an apical endpoint template was agreed, and discussion continues on how to revise the template accordingly while readily linking these effects to the apical endpoints (e.g. in IUCLID). A draft revised OHT 201 (including ontology updates) is under development, using Test Guidelines on skin sensitisation as a pilot case on what type of information should be captured and how to report it within the extended template. An expert consultation will take place by the end of 2018 to review the situation before contemplating the incorporation of other Test Guidelines.

40. Some technical and editorial improvements will be brought to the OHTs for release in October 2018. In particular, the Series of OHTs on use and exposure information will be updated to align them with the OECD Guidance document on harmonised product use categories issued in 2017.

Contact: *Bertrand Dagallier.*

Website: www.oecd.org/ehs/templates/

1.4.2. The International Uniform Chemical Information Database (IUCLID)

41. The International Uniform Chemical Information Database (IUCLID) is a software tool used to capture and store, submit, and exchange data on chemical substances according to the OECD Harmonised Templates for Reporting Chemical Test Summaries (OHTs). The objective of the OECD IUCLID User Group Expert Panel is to collect and discuss user needs in terms of the User Interface of IUCLID.

42. The IUCLID User Group Expert Panel met in October 2018 at which participants presented how their different jurisdictions are using IUCLID. In particular Australia showcased the customisation of IUCLID for use in its reformed assessment scheme including building an online web form on top of a IUCLID database. The Expert Panel and agreed a draft document on the customisation possibilities of IUCLID 6 (expected to be published in 2018). The Expert Panel discussed continuing activities and planned next steps for future IUCLID development (2018-2023) and agreed a draft revised mandate to take into consideration the increased opportunity for the Panel to support global harmonisation of data standards and data exchange and provide feedback on features related to IUCLID which support the use of or are integrated with IUCLID.

43. As well, the Expert Panel provided feedback for a new version of IUCLID 6 (v3) planned for release in October 2018. This new version includes a new user interface that requires only a standard web browser and updated formats to include the latest OECD Harmonised Templates, incorporate specific elements for microorganisms datasets, support of European Poison Centres notifications and Australian Industrial Chemicals assessment.

Forthcoming events:

- Meeting of the IUCLID User Group Expert Panel, 25-26 September 2019 (tentative), Paris, OECD

Contact: *Sally de Marcellus.*

2. Assistance with Governance

2.1. Test Guidelines

2.1.1. Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST)

44. The following new, updated or corrected Test Guidelines were considered adopted by OECD Council on 27 June 2018 and published:

New Test Guidelines:

Section 3: Environmental fate and behaviour

319A Determination of in vitro intrinsic clearance using cryopreserved rainbow trout hepatocytes (RT-HEP)

319B Determination of in vitro intrinsic clearance using rainbow trout liver S9 sub-cellular fraction (RT-S9)

Updated Test Guidelines:

Section 4: Health Effects

408 Repeated Dose 90-Day Oral Toxicity Study In Rodents

414 Prenatal Developmental Toxicity Study

438 ICE Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

442B Local Lymph Node Assay: BrDU-ELISA or FCM

442D In Vitro Skin Sensitisation assays addressing the AOP Key Event on Keratinocyte activation

491 STE Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage

402 Acute Dermal Toxicity Test: Fixed Dose procedure

Corrected Test Guidelines:

Section 4: Health Effects

412 Subacute Inhalation Toxicity: 28-Day Study

413 Subchronic Inhalation Toxicity: 90-Day Study

433 Acute Inhalation Toxicity Test: Fixed Concentration Procedure

442E *In Vitro* Skin Sensitisation assays addressing the Key Event on activation of dendritic cells on the Adverse Outcome Pathway for Skin Sensitisation

443 Extended One-Generation Reproductive Toxicity Study

451 Carcinogenicity Studies

452 Chronic Toxicity Studies

453 Combined Chronic Toxicity/Carcinogenicity Studies

492 Reconstructed human Cornea-like Epithelium (RhCE) test method for identifying chemicals not requiring classification and labelling

2.1.2. 30th Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT-30)

45. The 30th Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme was held at OECD on 24-27 April 2018. The WNT approved several new, updated and corrected Test Guidelines, as listed above. The WNT also approved a number of guidance documents and reports, supporting the use of Test Guidelines, published in July 2018 in the OECD Series on Testing and Assessment (see list below). New projects were taken on the work plan, including a project on developing Guiding Principles for Good Licensing Practices for Protected Elements in OECD Test Guidelines. The WNT also discussed ethical issues associated with the use of products of human origin (e.g. blood products) in Test Guidelines and it was agreed to hold a workshop in February 2019 on the topic to increase clarity and understanding of the issue and of any existing framework, guidance and texts that regulate the production, use and commerce of such products. In relation to several chronic toxicity tests, a concern was raised at the WNT that the dose selection is too low in current studies evaluated in Europe, and therefore do not seem to allow classification of chemicals. A sentence was added in TG 451, 452, 453 and 443 to that effect and it was agreed that a review of data from chronic toxicity studies and the dose selection process should be undertaken to inform discussion on the relevance of toxicokinetic data in the dose-setting process; this should be performed as a stand-alone project in the near future and several countries are interested in leading the activity. Finally, the WNT was updated on progress with the project to develop a Guideline on Defined Approaches for Skin Sensitisation; the project aims at standardising combinations of in vitro methods and fixed sources of information and data interpretation procedures to ultimately replace the LLNA animal test, while benefitting from Mutual Acceptance of Data. There are expectations that at least some of the Defined Approaches proposed will progress towards adoption by OECD in 2019.

46. Finally, a Memorandum of Understanding between the Guangdong Centre for Disease Control and Prevention and the OECD was signed on 24 April for cooperation at the technical level to support China's efforts to understand and get familiar with OECD Test Guidelines, especially in vitro test methods for the safety testing of chemicals.

2.1.3. Expert Group on Non-Genotoxic Carcinogenicity (NGTxC)

47. The Expert Group held its third meeting on 25-27 June 2018, at the OECD in Boulogne. This project is led by the United Kingdom, and its objective is to develop an Integrated Approach to Testing and Assessment (IATA), based on a combination of assays, mainly *in vitro*, to assist regulators in their assessments of Non genotoxic

Carcinogens (NGTxC). The project is at the stage of assay collection and their evaluation to identify promising assays for IATA inclusion.

2.1.4. Extended Advisory Group on Molecular Screening and Toxicogenomics (EAGMST)

48. The EAGMST met on 27-29 June 2018 at OECD in Paris. A joint session with the Working Party on Hazard Assessment was organised to review common projects and identify further needs and opportunities emerging from joint efforts. During the regular EAGMST meeting, 7 AOPs were approved which will be submitted for endorsement to WNT and WPHA in Q4 2018. The process followed for AOP reviews was discussed with the view to scale-up the capacities using professional means if possible, e.g. reviews by journals of well-known scientific societies; contacts will be established. The future of the AOP-Knowledge Base was briefly discussed, resources are needed to plan any further development; the co-chairs indicated that the Joint Meeting should be informed about this issue as the AOP Development Programme is a project they support. EAGMST also reviewed progress with the project on Omics Reporting Frameworks, and a set of presentations were made on high content imaging and high throughput transcriptomics (HTTr) for chemical bioactivity screening.

2.1.5. Expert Group on Developmental Neurotoxicity (DNT)

49. This project is led jointly by the EU (EFSA & JRC), Denmark and the United States. A call for case studies was announced in May 2018 and four case studies were reviewed that are relevant to hazard characterisation and screening for prioritisation. EFSA and the Danish EPA funded two research projects to generate data from a list of around 120 chemicals from a battery of in vitro tests and to optimise some of the methods. These data will serve as a basis for completing the case studies and draft a guidance document that aims at capturing the various steps of an IATA for DNT and how data can be combined and interpreted.

Forthcoming events:

- Meeting of the Advisory Group on Endocrine Disrupters Testing and Assessment (EDTA AG), 22-23 October 2018, OECD Paris,
- Workshop on the Use of Existing Data and Systematic reviews for Endocrine Disrupting Chemicals, 24 October 2018, OECD, Paris
- Meeting of the Validation Management Group for Ecotoxicity Testing (VMG-eco), 25-26 October 2018, OECD, Paris
- Meeting of the Validation Management Group for Non-Animal testing (VMG-NA), 6-8 November 2018, Seoul, Korea.
- Meeting of the Expert Group on Skin and Eye Irritation, 15-16 November 2018, OECD, Paris
- Joint meeting of the IATA Case Studies team and QSAR Toolbox Management Group to discuss QSARs in the context of defined approaches for skin sensitisation, 28 November, 2018, OECD, Paris
- Meeting of the Expert Group on Defined Approaches for Skin Sensitisation, 6-7 December 2018, OECD, Paris

- Meeting of the Joint WNT-WPMN Expert Groups on Ecotoxicity and fate testing of nanomaterials, 13-14 December 2018, JRC, Arona,Italy
- Meeting of the Expert Group on IP issues in OECD Test Guidelines, 13-14 February 2019, OECD, Paris
- Meeting of the Expert Group on Developmental Neurotoxicity, 5-6 March 2019, OECD, Paris
- Meeting of the Working Group of the National Coordinators of the Test Guidelines Programme (WNT-31), 9-12 April 2019, OECD, Paris.

***Recent publications in the* Series on Testing and Assessment**

- No. 23: (Second Edition). Guidance Document on aqueous-phase aquatic toxicity testing of difficult test chemicals.
- No. 39: (Second Edition). Guidance Document on Inhalation Toxicity Studies (No. 39)
- No. 150: (Second Edition). Guidance Document on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption.
- No. 160: (Third Edition). Guidance Document 160 on the Bovine Corneal Opacity and Permeability (BCOP) and Isolated Chicken Eye (Ice) Test Methods: Collection of Tissues for Histological Evaluation and Collection of Data on Non-Severe Irritants.
- **No. 188** (Second Edition). Streamlined summary document (SSD) in support of OECD Test Guideline 438 on the isolated chicken eye test method.
- No. 263: (Second Edition). Guidance Document on Integrated Approaches to testing and Assessment for Eye Irritation and Serious Eye Damage.
- No. 278: Report of the OECD Workshop on Intellectual Property Issues in OECD Test Guidelines.
- No. 280. Guidance on Determination of in vitro intrinsic clearance using cryopreserved rainbow trout hepatocytes (RT-HEP) or liver S9 sub-cellular fractions (RT-S9) from rainbow trout and extrapolation to in vivo intrinsic clearance.
- No. 281. Validation Report of the two new Test Guidelines on determination of in vitro intrinsic clearance using cryopreserved rainbow trout hepatocytes or liver S9 sub-cellular fractions.
- **No. 282**. Report of the peer-review of the validation of the LabCyte CORNEA-MODEL 24 EYE IRRITATION TEST.
- **No. 283**. Report of the validation study of the Local Lymph Node Assay BrdU-FCM (LLNA: BrdU-FCM) test method.
- **No. 284**. Report of the Peer Review of the validation of the Local Lymph Node Assay: BrdU-FCM (LLNA: BrdU-FCM) test method.
- **No. 285**. Feasibility Study for Minor Enhancements of TG 414 with ED Relevant Endpoints.

- No. 286. Guidance Document on Good In Vitro Method Practice.
- No. 287. Guidance Document on Use and Development of Tier-2 Laboratory Based Tests Used to Substantiate Claims for Efficacy of Biocide Treated Articles.

Contact: *Anne Gourmelon, Kanako Ito, Nathalie Delrue, Leon Van der Wal, Mar Gonzalez, Magdalini Sachana, Patience Browne and Christina Quaglio.*

2.2. Good Laboratory Practice and Compliance Monitoring

The 32nd meeting of the Working Group on GLP was held on 7-8 March, 2018 in Paris, France.

2.2.1. On-site evaluations

50. Under OECD's on-site evaluation activity, each GLP Compliance Monitoring Programme (CMP) in OECD and full adherent countries is evaluated every ten years. (The current ten-year phase began on 1 January 2018 and will conclude on 31 December, 2027.) These evaluations enhance confidence that receiving authorities are provided accurate and complete assessments of the conduct of non-clinical health and environmental safety studies and of the quality of the data. At the 32nd meeting of the Working Group on GLP, members reviewed evaluations of two CMPs – Estonia and Slovenia – that were conducted in 2017. The Working Group concluded that both CMP programmes fully comply with the 1989 Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice. For Estonia, this was their first completed evaluation and, thus, as of the date of the evaluation – 7 March 2018 – all OECD member countries and adherents to the Mutual Acceptance of Data (MAD) system must accept data generated in a test facility that is part of Estonia's monitoring programme if a test was conducted according to OECD Test Guidelines and OECD GLP. The following on-site evaluations are either completed or planned for 2018: Japan Workplace Chemicals (completed; 16-19 January); Germany (15-19 October); Czech Republic (29 October to 2 November); and Japan Medical Products (5-12 November). Six on-site evaluation visits are scheduled for 2019: United States (Medical Products); France (Medical products); Denmark (Chemicals and Pesticides); Denmark (Medical Products); Singapore; and Brazil.

2.2.2. Guidance Documents

51. ***Volume 4 of the Frequently Asked Questions (FAQ)*** document was published on 28 February, 2018. The FAQ responds to comments gathered from industry and trade associations and quality groups on areas on GLP compliance that may be of concern due to a lack of harmonisation across governments. Volume 4, in particular, focuses on the following topics raised by industry regarding: Sponsors; Contract Research Organisations (CROs); Sub-contractors; Archives; Information Technology (IT); Biotechnology/GMOs; and other miscellaneous issues.

52. ***Volume 5 of the FAQ*** is being developed to describe monitoring authority expectations of test facility management concerning the selection of test sites and claims of GLP compliance for study phases. The document is being developed by a drafting group under the leadership of the Netherlands and the United Kingdom. The FAQ will provide guidance to test facility management on the implications of selecting a test site

that is not a member of a national GLP compliance monitoring programme or has not been inspected by a national compliance monitoring authority. At the 32nd meeting, the Working Group discussed a second draft of the document and agreed that it would be useful to seek additional clarity from Working Group members regarding the questions/answers and how members would like them addressed. A revised version of the document will be considered at the next Working Group meeting in 2019.

53. An ***Advisory Document on the Management and Characterisation and Use of Test Items*** was published on 19 April, 2018. This document provides clarity for test facilities on the expectations of national GLP compliance monitoring authorities regarding how test items are transported, received, identified, labelled, sampled, handled, stored, characterised, archived and disposed according to the Principles of GLP. It also aims to promote a consistent approach that is appropriate to the objective of the study and the nature of the test item.

54. An ***Advisory Document on Data Integrity - Definition and Guidance for Industry*** - is being developed by a drafting group under the leadership of the UK. The 32nd meeting of the Working Group reviewed the latest draft and members were invited to provide additional comments after the meeting. If, following this round of review, the document does not require any substantive changes, the revised draft will then be posted on the OECD's public website for comment, before a final draft is produced for circulation and approval by the Working Group and eventual publication.

55. A new ***Guidance Document for Receiving Authorities*** for verifying the GLP status of submitted studies is being developed by a drafting group under the leadership of the Netherlands. (A receiving authority is a national body which reviews test submissions and is responsible for the assessment and management of chemicals.) The objective of the new guidance is to promote an adequate and time-efficient evaluation of the GLP status of submitted data as well as the GLP status of test facilities that generate non-clinical health and environmental data used for hazard and risk assessments. The Guidance may also help reviewers determine whether it is necessary to request a study audit and/or test facility inspection before the data can be accepted. The latest draft was reviewed at the March, 2018 Working Group meeting. Based on the comments raised, a second version will be prepared for review by the Working Group followed by a review by national receiving authorities.

56. A German translation of Advisory Document No. 17: *Application of GLP Principles to Computerised Systems* was posted on the public site on 27 August, 2018.

57. The ***14th OECD GLP training course*** will be held in Cape Town, South Africa from 7-10 October, 2019. A steering group organising the training course met on 6 March before the 32nd meeting of the Working Group and agreed the scope and plan for the training course, which was later agreed by the Working Group.

Forthcoming events:

- 33rd Meeting of the Working Group on GLP – Paris, France, 5-7 March, 2019
- 14th OECD Training Course for GLP Inspectors – South Africa, 7-10 October, 2019

Recent publications:

- Version 4 of the OECD Good Laboratory Practice: Frequently Asked Questions (FAQ), February 2018.
- Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items, April 2018

2.3. Mutual Acceptance of Data

58. There are six partner countries that are full adherents to MAD: **Argentina**, **Brazil**, **India**, **Malaysia**, **Singapore** and **South Africa**. Non-clinical health and environmental safety data generated in these countries must be accepted for regulatory purposes in OECD and other adhering countries. At the moment, full adherence for Argentina only applies to industrial chemicals, pesticides and biocides.

59. The Working Group on GLP implements on-site evaluation visits of national compliance monitoring programmes which are provisional adherents to MAD and are ready to be considered for full adherence. Currently, **Thailand** is a provisional adherent and an on-site evaluation team from Spain, Belgium and India visited the GLP Compliance Monitoring Programmes in Thailand in January, 2012. The report from the visit was considered at the 27th meeting of the Working Group on GLP (16-18 April, 2013). The Working Group meeting in April 2015 agreed that a follow-up visit to Thailand could be conducted once the follow-up team - Belgium, India and the Netherlands – felt it was prudent to do so. A follow-up visit was held on 3-7 September, 2018. The evaluation will be considered at the 33rd meeting of the Working Group (5-7 March, 2019).

60. The Secretariat continues to work with several other countries in view of their possible provisional adherence to the MAD Council Acts. In particular, the Secretariat along with Working Group delegates from the Netherlands and Malaysia organised a seminar that was held in Jakarta, Indonesia from 25-27 April 2018. The objectives of the seminar were to brief relevant government agencies and test facilities in Indonesia about GLP, GLP compliance monitoring and MAD, and to discuss possible next steps for future co-operation on MAD.

Contact: Richard Sigman and Kanako Ito.

Website: www.oecd.org/env/ehs/mutualacceptanceofdatamad.htm

2.4. Methodologies for evaluating the performance of chemicals management schemes

61. Canada has developed a background report on current performance measurement approaches for chemical management schemes in OECD countries. The draft report was discussed at the Joint Meeting in November 2016 and at the Joint Meeting in February 2018. The report will be released in Q4 of 2018. No further activity will continue on this topic at this time.

Contact: Eeva Leinala.

2.5. Evaluation and updating of OECD legal instruments ("acquis") on chemicals

62. Following the adoption by the 57th Joint Meeting in February 2018, the revised Council Act on PRTRs was adopted by Council in April 2018: Recommendation of the Council on Establishing and Implementing Pollutant Release and Transfer Registers (PRTRs) [C(2018)5].

63. Following the adoption by the 57th Joint Meeting in February 2018, the Council Act on the Co-operative Investigation and Risk Reduction of Chemicals was adopted by Council in May 2018: Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Chemicals [C(2018)51].

64. At the 57th Joint Meeting, members noted that issues associated with intellectual property rights (IPR) are becoming increasingly prominent in the context of data used for safety assessments of chemicals, together with the increasing amount of such data becoming publicly available, and requested that the Secretariat investigate the possibility for OECD to address these issues in a holistic manner. To support this effort, an *Ad Hoc* Group was established, consisting of members from government, industry and civil society. The Group has prepared a scoping study for consideration at the 58th Joint Meeting, addressing issues of IPR associated with chemical safety data as well as how OECD can address these issues, what the output should be and a schedule for developing that output.

2.5.1. *Contact:* *Eeva Leinala, Takaaki Ito, Marit Hjort and Richard Sigman*

Website: **www.oecd.org/chemicalsafety/oecd-council-acts.htm**

2.6. Methodologies for assessing the costs and benefits of managing chemicals

65. The Joint Meeting and the Environmental Policy Committee's Working Party on Integrating Economic and Environmental Policies are collaborating on the design of coordinated valuation studies. This will entail the conduct of one or several valuation studies (e.g. studies surveying the willingness to pay to avoid certain health impacts or environmental outcomes) with a focus first on for morbidity endpoints relevant to chemicals exposure in different OECD countries. The concept is to coordinate the development of the survey instrument, implement the survey using the consolidated instrument and analyse and compare the valuation results. Additional endpoints, including environmental endpoints, could then be considered. A project team for this initiative has been established and discussions on the workplan and funding are underway.

66. Five case studies on valuation in the context of regulation - phthalates, PFOA, mercury, formaldehyde and NMP - were published, along with a workshop report, stemming from the workshop held in August 2017 in Ottawa, Canada focused on examining case studies of valuation of risk management actions on specific chemicals.

67. In addition, the Joint Meeting agreed to establish an expert group on Risk Management Discussions including Socioeconomic Analysis. The expert group has been established and will focus on sharing of case studies and approaches undertaken in different countries.

68. At the 57th Joint Meeting, members supported the development of an update of the 2010 report "Cutting Costs in Chemicals Management: How OECD Helps Governments and Industry". Following the meeting, a Steering Group was established with representatives from Colombia, the European Commission, Italy, the Netherlands, the UK, the industrial chemicals and pesticides industries, the consulting firm RPA and the Secretariat. The Steering Group developed questionnaires to collect relevant data from governments, and industry (industrial chemicals, pesticides and biocides) and those questionnaires were distributed in March 2018. Based on the information collected, as well as additional data collected from the open literature and OECD statistics and modelling databases, a draft report has been prepared for consideration at the 58th Joint Meeting. Publication is anticipated by early 2019.

Recent publications in the Series on Risk Management:

- No. 47: Economic Valuation in Formaldehyde regulation
- No. 46: Socio-economic Assessment of Phthalates
- No. 45: Economic assessments of the benefits of regulating mercury
- No. 44: Economic valuation in 1-Methyl-2-pyrrolidone (NMP) regulation
- No. 43: Economic assessment and valuations of environmental and health impacts caused by Perfluorooctanoic acid (PFOA) and its salts
- No. 42: Workshop Report: OECD Workshop on the Best Practices in Assessing the Social Costs of Selected Chemicals (Annex 1).

Contact: Eeva Leinala, Richard Sigman and Marit Hjort

Website: www.oecd.org/chemicalsafety/sacame.htm

3. Support for Capacity Building

3.1. eChemPortal

69. The next release of eChemPortal is planned for the end of October 2018 with alignment of the eChemPortal catalogue with the revisions to the OECD Harmonised Templates and GHS. This will be a major release of eChemPortal v2.0 including updated search fields in the user interface, property data catalogue, data notification ticket XML (though the current notification ticket XML will still be accepted), a new data migration module, and data source data migrated to the updated catalogue.

70. The Steering Group for the Development of the Global Portal met in April 2018 and discussed modernisation of the User Interface architecture of eChemPortal and design, as well as functional requirements (work to cover 2019-2020), and planned efforts in 2019 to focus on eChemPortal participation and use.

Forthcoming events:

- 33rd Meeting of the Working Group on GLP – Paris, France, 5-7 March, 2019
- 14th OECD Training Course for GLP Inspectors – South Africa, 7-10 October, 2019

Contact: *Sally de Marcellus.*

Website: **www.oecd.org/ehs/echemportal/**

3.2. Dissemination of OECD Products

3.2.1. IOMC Toolbox

71. The IOMC Toolbox is a problem-solving tool that enables countries to identify the most appropriate and efficient national actions to address specific national problems related to chemicals management.

72. A more user-friendly new platform of the IOMC Toolbox is being developed. The new homepage was published in October and the whole platform should be put live in Q1 2019.

73. The OECD continues to promote the IOMC Toolbox, with the aim of dissemination and receiving feedback on the tool. Recent events include:

- a webinar presentation at the meeting of the Executive Programme on Integrated Chemical Management, London, United Kingdom, 26 September 2018.

Contact: *Sylvie Poret, Valérie Frison*

Website: **http://iomctoolbox.oecd.org**

3.2.2. Implementation of the OECD Strategy on Development

74. Since the last Joint Meeting, work focused on capacity-building. On industrial chemicals, the series of webinars to help Peru establish their industrial chemicals management system was completed with a webinar in June 2018 on mainstreaming chemicals management across Ministries. On pesticides, a series of workshops on compliance and enforcement of pesticide regulations in Sahel and West African countries has started: a first workshop targeted to inspectors and heads of inspection services of 17 countries of the region was held in Dakar, Senegal, in March 2018.

Contact: *Sylvie Poret, Valérie Frison*

Website: **www.oecd.org/env/ehs/development-cooperation-sound-management-chemicals.htm**

4. Facilitation of Risk Reduction

4.1. Tools and approaches to support decision-making for the substitution of hazardous chemicals

75. The OECD Ad Hoc Group on the Substitution of Harmful Chemicals organised a workshop on Approaches to support Substitution and Alternatives Assessment, in Paris, on 2-3 May 2018. The goal of this workshop was to exchange experiences on policy, regulatory and other approaches used to support alternatives assessment and the substitution of chemicals of concern. To inform the workshop discussions, a Cross-Country Analysis of Approaches for Alternatives Assessment and Substitution had been prepared by collecting experiences amongst countries through a questionnaire. A report from the workshop together with the cross country analysis are being finalised and will be sent to the Joint Meeting for declassification during the course of November 2018.

76. The May workshop identified a number of gaps in moving the field of substitution and alternatives assessment forward and concluded that the Ad hoc Group could engage on a number of projects as follows:

- Share information on substitution and alternatives assessment priorities across countries
- Communication of regulatory, policy and other approaches for substitution;
- Identify key considerations for 'safer' chemicals including for decision-analysis/risk trade-offs;
- Share approaches and build collective capacity;
- Continue to identify information that should be shared and ways to do so.

77. Following a teleconference, the Ad Hoc Group agreed to proceed with the above activities.

Contact: *Eeva Leinala, Marie-Ange Baucher*

Websites: **http://www.oecd.org/env/ehs/risk-management/**
www.oecdsaatoolbox.org

4.2. Risk Reduction (general methodologies and policies and analysis of approaches as well as on specific chemicals)

4.2.1. Perfluorinated chemicals

78. The OECD/UNEP Global Perfluorinated Chemicals Group was established in 2012 to facilitate the exchange of information on PFASs (Per and Poly- Fluoro Alkyl Substances) and to support a global transition towards safer alternatives.

79. The Group published in May 2018 a **new list of Per- and Polyfluoroalkyl Substances (PFASs)** based on a comprehensive analysis of information available in the public domain. In total, 4730 PFAS-related CAS numbers have been identified and categorised in this study, including several new groups of PFASs that fulfil the common definition of PFASs (i.e. they contain at least one perfluoroalkyl moiety) but have not yet been commonly regarded as PFASs. This list is an update from a list published by the OECD in 2007.

80. The Group has currently three projects underway, on:

- **PFASs and Alternatives - Commercial Availability and Current Uses**: the project aims to provide information on current uses of alternatives to PFAS in the production of products and articles in three industry sectors: textile (including shoes); firefighting foam; and food packaging. A questionnaire was prepared to collect information from stakeholders on alternatives and their use(s); performance and related costs; uptake/market penetration; and challenges to their development. Twelve responses were received to the questionnaire from countries and industry. .
- **Expanding the Current PFAS Terminology**: the goal of this project is to provide guidance to all stakeholders so that they can communicate around PFASs using the same language. More specifically, this project aims to systematically expand the current PFASs terminology to solve existing issues within the current terminology and accommodate newly identified PFASs. The group is currently working on scoping the project further;
- **Risk Reduction Approaches across Countries:** information available on the OECD PFASs WebPortal on approaches across countries for PFASs risk reduction is being updated. Countries are providing updated information through a questionnaire.

81. Three webinars were organised: one to launch the new list of PFASs in June 2018, one on Best Environmental Practices in Textiles with a presentation by Chemours in September 2018, and one in October 2018 to present conclusions from the MIDWORE-LIFE project. .

4.2.2. Risk management discussions including socioeconomic analysis

82. The expert group on Risk Management Discussions, Including Socioeconomic Analysis aims to share experiences and develop lessons learnt on a range of topics such as health and environmental impacts of regulation, including economic valuation of impacts; cost of regulating substances; and economic assessments in chemicals management.

83. The expert group was established in early 2018. The group discussed through a first teleconference how to best start activities. It was agreed to organise a face to face meeting on 22-23 January 2019. Topics to be discussed at the meeting are under consideration.

Forthcoming events:

- Expert group on Risk Management Discussions, including Socioeconomic Analysis 22-23 January 2019.

Recent publications in the Series on Risk Management:

- No. 39: New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs) and its accompanying methodology report

Contact: *Eeva Leinala, Marie-Ange Baucher*

Websites: www.oecd.org/chemicalsafety/risk-management/
www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/

5. Development of Instruments for the Assessment and Management of Pesticides and Biocides and the fight against their Illegal Trade

5.1. Pesticides

84. The pesticide **Residue Chemistry Expert Group (RCEG)** developed a **Guidance Document for Residues in Rotational Crops**, which was published in May 2018. The same group is currently working on an update of **TG 509 - Crop Field Trials** and a revision of the **Guidance Document on Definition of Residue**. A face-to- face meeting to discuss the definition of residue that will bring together OECD, FAO and WHO experts will take place in December 2018 in Geneva.

85. In the area of the illegal international trade of pesticides, the **OECD Network on Illegal trade of Pesticides (ONIP)** and Working Group on Pesticides approved a Best Practice Guide (BPG) to address issues related to fighting illegal trade, and to strengthen a "Global Alliance" against illegal trade of pesticides. As part of this Alliance, a draft Council Recommendation has been developed which calls for, among other things, establishing or strengthening national procedures aimed at countering the illegal trade of agricultural pesticides in line with the BPG. The draft Recommendation was also approved by ONIP and the WGP and the 58th Joint Meeting will be invited to declassify the BPG and approve the draft Recommendation and that it be transmitted to Council for Adoption. Final adoption by Council is anticipated in late 2018 or early 2019.

86. In June 2018, the Working Group on Pesticides reviewed the use of the OECD Pesticide Information Notification System, launched in December 2017 to efficiently communicate pesticide-related information confidentially among regulatory authorities of OECD member countries, the European Commission (EC) and European Food Safety Authority (EFSA). The Working Group agreed to review the use of the system again in 2019.

87. The public website was updated with information about the regulatory approaches adopted by OECD member countries to mitigate pesticide risks to insect pollinators.

88. Work is continuing within the Pesticides Programme and the Test Guidelines Programme on test methods for the homing flight test on honeybees after single exposure to sub-lethal doses.

89. The Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD) continues its activities regarding the Global Harmonised Submission Transport Standard (GHSTS) http://www.oecd.org/chemicalsafety/submission-transport-standard/. The GHSTS specifies how to assemble electronic files required in the evaluation of submissions for any pesticide package. The Expert Group is currently focusing on maintaining the Standard (i.e., consider modification requests received) and plans to finalise GHSTS version 2 by the end of 2018, extended to allow use for products other than plant protection products (e.g., feed additives) as well as to update the GHSTS Governance document. The Expert Group also is providing feedback on supporting tools

to assist implementation of the GHSTS. Canada upgraded the "Minimally Viable Product" of a GHSTS "e-dossier" builder which can create GHSTS XML to version v.1.5 which allows flexibility for future enhancements. A small analysis project is on-going by Industry on differences and potential synergies between the GHSTS and IUCLID. BIAC released a new version of the GHSTS Desktop Viewer, "eSubmission viewer" 02.01.00.

90. As regards the work of the Expert Group on Bio-Pesticides (EGBP) - previously called the Bio-pesticides Steering Group (BPSG) – the Guidance Document on the Assessment of Equivalence for Microbials was published in May 2018 and the Working Document on the Risk Assessment of Secondary Metabolites of Microbial Biocontrol Agents is anticipated to be published in November 2018. The Report of the 8th EGBP Seminar on "Niche Uses of Highly Specific Biocontrol Agents" was published in March 2018. The Report of the 9th EGBP Seminar on "Testing methods for micro-organisms" is under review by the Expert Group and is expected to be published in 2019.

91. The **Ad Hoc Expert Group on RNAi-based Pesticides** is developing a working paper which will document the current state of knowledge of and regulatory considerations by agencies in OECD member countries related to the effects on non-target organisms from exposure to RNAi-based pesticides, including environmental fate of these pesticides. (These pesticides cause post-transcriptional gene silencing through an RNA interference (RNAi) mechanism.) For this project, RNAi-based pesticides will not include plants genetically engineered to target pest species by an RNA interference mechanism, while still recognising that data available on these GM plants may be useful in evaluating other types of RNAi-based products. The working paper is expected to be published in 2019. A conference on "Regulation of Externally Applied dsRNA-based Products for Management of Pests" is tentatively scheduled for 10-12 April 2019, in Paris.

92. Work is underway to develop an updated version of the **Table of Contents/Crosswalk in the OECD Dossier Guidance document**, which was last updated in 2005. At the June, 2018 WGP meeting, a revised document was developed for review by delegates. Next steps will be to establish new OECD data point numbers based on the additional data requirements that were submitted by the countries and complete the cross-walk.

Forthcoming events:

- 13-14 February 2019, OECD Network on Illegal Trade of Pesticides (ONIP) meeting (OECD, Paris, France)
- 14 - 15 May 2019, EGEEPD meeting (OECD, Paris, France)
- 24 June 2019, EGBP seminar (OECD, Paris, France)
- 25 June 2019, EGBP meeting (OECD, Paris, France)
- 26 June 2019, Risk Reduction Seminar – *tentative* - (OECD, Paris, France)
- 27 to 28 June 2019: Working Group on Pesticides (OECD, Paris, France)

Recent publications in the Series on Pesticides:

- No. 97: Guidance Document on Residues in Rotational Crops

- No. 96: Guidance Document for the Assessment of the Equivalence of Technical Grade Active Ingredients for Identical Microbial Strains
- No. 95: Report of the 8th Biopesticides Steering Group Seminar on Niche Uses of Highly Specific Biocontrol Products (Annex)

Contact: *Richard Sigman, Leon van der Wal, Magdalini Sachana and Sally de Marcellus*

Website: **www.oecd.org/env/pesticides**

5.2. Biocides

93. The Expert Group on Claims Development for biocides Treated Articles (EGCDTA) has started to collect a common library of available legislation in OECD countries as well as of distinctive claims and has started with the development of possible principles of claims development.

94. The Expert Group on Efficacy of Biocides to Treat Articles (EBTA) has developed a draft Guidance Document for Tier 2 laboratory-based tests to substantiate claims for efficacy of biocide treated articles including porous surfaces (textiles) and non-porous surfaces (plastics). The draft Guidance Document contains two detailed example protocols: simulated splash test on textiles and plastics and non-suspended inoculum method to simulate hand contact and was published in July 2018. Possible follow-up activities of the EBTA are under discussion in the WGB.

95. The WGB was asked to review a first draft of the Guidance Document on laboratory assays for evaluating the efficacy of biocides against bed bugs in June 2018. Germany is reviewing the comments received.

96. A project to establish an inventory of available methodologies for a Sustainable Use of Biocides in OECD countries was initiated in May 2017. Best Practice Codes (BPCs) for certain biocidal uses considered to be particularly relevant were collected and differences and commonalities were discussed during the October 2017 WGB meeting. The lead country (Germany) is completing the collection of BPCs.

97. The Expert Group on Biocides Chemistry (EGBC) continues working on the development of two documents: 1) Guidance for flammability testing; and 2) Document on waiving and bridging of physical chemistry studies.

Forthcoming events:

- October 2019, 3rd Meeting of the Working Group on Biocides, Seoul, Korea.

Recent publications in the Series on Biocides:

- No. 13: Guidance Document on Use and Development of Tier-2 Laboratory Based Tests Used to Substantiate Claims for Efficacy of Biocide Treated Articles.

Contact: *Sylvie Poret, Leon van der Wal and Haeseung Kim.*

Website: **www.oecd.org/chemicalsafety/pesticides-biocides/biocides.htm**

6. Development of Instruments to assist countries in dealing with releases of hazardous chemicals from installations and products

6.1. Chemical Accidents

98. The Working Group on Chemical Accidents published on 11 June 2018 a **Guidance on Change of Ownership in Hazardous Facilities**. This Guidance is a concise document providing a framework to assist stakeholders to identify, understand and minimise the risks during and after a change of ownership at a hazardous facility, and help make the change of ownership a better informed process. The guidance provides:

- • A list of risk drivers prior, during and after the change of ownership;
- • A set of self-assessment questions for the original owner and for the prospective owner so that they can evaluate how well their organisation is managing the ownership change;
- • A "template for transparency" as a structured approach to carrying out technical due diligence with a list of documents and information which those selling a facility should be expected to provide;
- • A list of factors for the regulators to consider before, during and after the change of ownership.
- A workshop report was published in March 2018 on **Developing a Methodology to Quantify the Benefits of Regulations for Chemical Accidents Prevention, Preparedness and Response**. The report provides a snapshot of opportunities and challenges in measuring the benefits and costs of chemical accidents prevention, preparedness and response regulations, and an overview of countries experience. The workshop report concludes that a guidance providing a framework of agreed-upon quantitative and qualitative benefits would help decision-making on regulation and the development of policy. This guidance is now under development.

99. A joint OECD/UN Workshop on Natech Risk Management has been organised on 5-7 September 2018 in Potsdam, Germany. The overall objective of the workshop was an information exchange between OECD Member and Non-Member countries, with a particular focus on sharing good practices, and examining how Natech risks can be better integrated in risk management, emergency planning, disaster management and risk communication. More information about the event can be found on the workshop web-site at http://www.natech-workshop.de .

Forthcoming events:

- 29th Meeting of the Working Group on Chemical Accidents, October 2019, OECD Headquarters, Paris.

Recent Publications in the Series on Chemical Accidents:

- No 31 - Guidance on Change of Ownership in Hazardous Facilities
- No 30 - Workshop Report: Developing a Methodology to Quantify the Benefits of Regulations for Chemical Accidents Prevention, Preparedness and Response

Contact: Peter Kearns, Marie-Ange Baucher

Website: **www.oecd.org/chemicalsafety/chemical-accidents/**

6.2. Pollutant Release and Transfer Registers (PRTRs)

100. The Working Group on Pollutant Release and Transfer Registers (WG-PRTRs) focuses on i) improving PRTRs, ii) harmonising PRTRs across the world, and iii) enhancing the use of PRTR data.

101. To assist countries in improving and harmonising their PRTRs, the WG-PRTRs is currently reviewing Part 2 (diffuse sources) of the guidance document on release estimation techniques (Resource Compendium of PRTR Release Estimation Techniques) and it is expected to be finalised in Q4 2018. In addition, the WG-PRTRs has started to review and update the harmonised list of pollutants and reporting sectors. The WG-PRTRs will also exchange experiences on outreach activities by the member countries for assisting other countries to establish and implement their PRTRs at the Second Meeting of the WG-PRTRs in November 2018.

102. The WG-PRTRs is also conducting several projects to promote the use of PRTR data, including using PRTR data for tracking progress towards the UN Sustainable Development Goals (SDGs) and collecting information and sharing good practice on PRTR data application for local environmental management, which will be discussed at the Second Meeting of WG-PRTRs and is expected to be finalised by the end of 2018. Further use of PRTR data will be presented and discussed in the Second Meeting of WG-PRTRs and the Third Global Round Table on PRTRs held jointly by UNECE and the OECD in November 2018.

Forthcoming events:

- Second Meeting of the Working Group on PRTRs (November 5-6, 2018, Geneva)

Contact: Takaaki Ito

Website: **www.oecd.org/chemicalsafety/pollutant-release-transfer-register/**

7. Development of Instruments to assist in the harmonisation of regulatory oversight of the safety of products of modern biotechnology

7.1. Environmental Safety

103. The Consensus Document on the Biology of mosquito Aedes aegypti was issued in June 2018, the second publication in the Series on Harmonisation in Regulatory Oversight in Biotechnology to specifically address an animal species (following Atlantic salmon in 2017). This mosquito is of major public health concern, being the main vector of viruses responsible for diseases such as yellow fever, dengue fever, Zika fever and chikungunya. In recent years, new strains of Ae. Aegypti transformed by biotechnology have been tested in some countries and locally released in the context of mosquito control programmes. The project for developing the document was co-lead by Mexico, Brazil, and the ILSI Research Foundation. The publication describes the taxonomy, morphology, reproductive biology, genetics and ecology of the mosquito species, as well as control measures and human and animal health affected by mosquitoes. These scientific findings are useful for the risk/safety assessment of new strains of the mosquito species and their impacts on the environment. The document constitutes a solid reference for commercial applicants intending to use genetically-engineered organisms, regulators and risk assessors, as well as the wider scientific community.

104. The experts in charge of preparing the document on "Environmental Considerations for Risk/Safety Assessment for the release of Transgenic Plants" have accelerated their work since their 8th meeting in Berlin in September 2017. The project is led by Canada and the Bureau of the Working Group. The first full draft consensus document, constituted of seven individual consideration sections and introductory texts, was issued for comments in March 2018 and discussed at the 9th expert meeting in June 2018. Further progress is being made for finalising the document along the defined work plan, with publication expected in 2019.

105. Other developments include the preparation of several documents on:

- Mosquito *Anopheles gambiae* biology (co-leads: NEPAD African Biosafety Network of Expertise, ILSI-RF), for which a kick-off expert meeting is planned in the first quarter of 2019 in an African country (tbc).
- Five Crop species biology documents: Apple (with Belgium and Germany as co-leads, a second draft being prepared); Wheat (revision; co-leads: Australia, United States), Maize (co-leads: Mexico, South Africa and Kenya) and Rice (led by Japan), for which Ad hoc expert groups are being established; Safflower (lead: Australia), for which the project proposal was agreed at the 32nd WG meeting in June 2018 and an operational plan is under review by the WG.
- Micro-algae (project led by the Steering Group on micro-organisms chaired by the United States), for which the operational plan is being refined.

106. The **OECD BioTrack Product Database**, containing information on transgenic plants approved for being cultivated or used in foods and feeds, continued to be completed. Over the February-October 2018 period, information was updated for 110 varieties (addition of further approvals to existing entries) while 12 new varieties were added, including for apple and safflower species for the first time. The inputs were provided by Australia, Canada, Japan, Australia/New Zealand, the European Union, and two new countries to the Database: the Philippines and Viet Nam. Currently, the database includes a total of 285 varieties of genetically-engineered plants from 17 crops (and flower) species, information provided by 14 delegations (9 OECD Members, the European Union and 4 non-Members).

107. Genome editing techniques have emerged as a major topic related to applications of biotechnology. The *OECD Conference on Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation* was held on 28-29 June 2018 to address concerns associated with the use of this new technology in agriculture. About 200 people from academics, industry, policy makers and other stakeholders participated in this event. The conference information including the programme, speakers, abstracts, presentation files and other related information is available online (**http://www.oecd.org/environment/genome-editing-agriculture/**). The conference proceedings are being prepared for publication.

Forthcoming events:

- 9th face-to-face meeting of Steering Group for "Environmental Considerations for Risk/Safety Assessment for the release of Transgenic Plants", 21-22 June 2018;
- 32nd meeting of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, 25-27 June 2018, OECD, Paris;
- OECD Conference on Genome Editing: Applications in Agriculture – Implications for Health, Environment and Regulation, 28-29 June 2018, OECD, Paris.

Recent publications in the ***Series on the Harmonisation of Regulatory Oversight in Biotechnology***

- **No 65:** Consensus Document on the Biology of mosquito Aedes aegypti (2018); also published in the Compendia Series as:
- OECD (2018), Safety Assessment of Transgenic Organisms in the Environment, **Volume 8**: OECD Consensus Document of the Biology of Mosquito Aedes aegypti, Harmonisation of Regulatory Oversight in Biotechnology, OECD Publishing, Paris. **http://dx.doi.org/10.1787/9789264302235-en**
- **Biotechnology Update' (ICGB Newsletter) No.33**, June 2018, prepared by EHS for the OECD Internal Co-ordination Group for Biotechnology (ICGB) and compiling inputs from several Directorates (ENV, STI, TAD), the Global Relations Secretariat and the International Energy Agency/Renewable Energy Division.

Contact: *Ryudai Oshima, Yoko Takasu, Bertrand Dagallier, Peter Kearns*

Website: **www.oecd.org/env/ehs/biotrack/**

7.2. The Global Forum on Biotechnology

108. Collaboration continues with key non-member partners and other international organisations involved in biosafety, in particular on the occasion of the plenary meetings of the OECD Working Groups on i) the Harmonisation of Regulatory Oversight in Biotechnology, and ii) the Safety of Novel Foods and Feeds, as well as the Conference on Genome Editing Applications in Agriculture held back-to-back at the OECD in June 2018. The Conference provided further support for participation of non-members. In total, these events were attended by delegates from Argentina, Brazil, China (P.R. of), Colombia, India, Kenya, Paraguay, Philippines, South Africa, Uruguay, Viet Nam, the African Biosafety Network of Expertise (AU-NEPAD), FAO, CIAT and the ILSI Research Foundation.

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7.3. Safety of Novel Foods and Feeds

109. The Working Group for the Safety of Novel Foods and Feeds continued to develop consensus documents on the composition of: Cowpea (*Vigna unguiculata*) to be finalised by the end of 2018 (lead: Australia); Apple (*Malus domestica*) expected for publication early 2019 (project co-led by Germany and Canada); and to revise the Maize (*Zea mays*) document initially issued in 2002 (lead: United States). Two new projects were recently launched, i) to revise the current Potato (*Solanum tuberosum*) composition publication of 2002 (lead: Sweden), and ii) to develop a new document for Cucurbits species (squashes, pumpkins, zucchinis and gourds), under the leadership of Mexico.

110. Other topics for potential projects are being discussed, e.g. composition of high glucosinate/high erucic acid rapeseed, emerging feed ingredients, or the 'safe-by-design' concept applied to biotechnology products. The products derived by new breeding techniques (including genome editing) and their possible impact on safety assessment and regulation are also meeting strong interest, as well as the 'omics' techniques and massive parallel sequencing for comparative crop analysis. The Bureau continues to explore suggestions for other projects and will establish priorities.

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Forthcoming events:

- 26th Meeting of the Working Group for the Safety of Novel Foods and Feeds, OECD, 4-5 April 2019

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Website: www.oecd.org/env/ehs/biotrack/